

What is claimed is:

1. A method of regulating smooth muscle tone in a subject, comprising the introduction and expression of a DNA sequence comprising a smooth muscle specific promoter, smooth muscle alpha actin (SMAA), operably linked to a sequence encoding a potassium channel protein that regulates smooth muscle tone, in a sufficient number of smooth muscle cells of the subject to regulate smooth muscle tone in the subject.
2. A method of regulating smooth muscle tone in a subject, comprising the introduction and expression of a DNA sequence encoding a voltage-dependent potassium channel protein that regulates smooth muscle tone, in a sufficient number of smooth muscle cells of the subject to regulate smooth muscle tone in the subject.
3. A method of regulating smooth muscle tone in a subject, comprising the introduction and expression of a DNA sequence encoding a non-large conductance, calcium-sensitive potassium channel protein that regulates smooth muscle tone, in a sufficient number of smooth muscle cells of the subject to regulate smooth muscle tone in the subject.
4. The method of claim 1, 2 or 3, wherein the smooth muscle cells are arterial smooth muscle cells, venous smooth muscle cells, or visceral smooth muscle cells.
5. The method of claim 4, wherein the smooth muscle cells are located in the bladder, blood vessel wall, gastrointestinal tract, bronchi of the lung, endopelvic fascia, penis, prostate gland, ureter, urethra, uterus, or vas deferens of the subject.

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6. The method of claim 4, wherein the visceral smooth muscle cells are bladder smooth muscle cells, corporal smooth muscle cells, gastrointestinal smooth muscle cells, prostatic smooth muscle cells, or urethral smooth muscle cells.

7. The method of claim 1, 2 or 3, wherein the DNA sequence is genomic DNA or cDNA.

8. The method of claim 1, 2 or 3, wherein the potassium channel protein modulates relaxation of the smooth muscle.

9. The method of claim 8, wherein the potassium channel protein modulates relaxation of corporal smooth muscle.

10. The method of claim 1, wherein the potassium channel protein is maxi-K,  $K_{ATP}$ , Kv1.5, or SK3.

11. The method of claim 1, wherein the smooth muscle cells are corporal smooth muscle cells and the potassium channel protein is maxi-K.

12. The method of claim 2, wherein the voltage-dependent potassium channel protein is Kv1.5.

13. The method of claim 3, wherein the non-large conductance, calcium-sensitive potassium channel is an intermediate conductance calcium-sensitive potassium channel.

14. The method of claim 3, wherein the non-large conductance, calcium-sensitive potassium channel is a small conductance calcium-sensitive potassium channel.

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15. The method of claim 14, wherein the small conductance calcium-sensitive potassium channel is SK3.

16. The method of claim 2 or 3, wherein the DNA sequence further comprises a promoter operably linked to the sequence encoding the potassium channel protein.

17. The method of claim 16, wherein the promoter is a smooth muscle specific promoter.

18. The method of claim 17, wherein the smooth muscle specific promoter is smooth muscle alpha actin (SMAA).

19. The method of claim 1, 2 or 3, wherein the DNA sequence is introduced by a method selected from the group consisting of instillation therapy, electroporation, DEAE Dextran, cationic liposome fusion, protoplast fusion, creation of an *in vivo* electrical field, DNA-coated microprojectile bombardment, injection with recombinant replication-defective viruses, homologous recombination, nebulization, and naked DNA transfer.

20. The method of claim 19, wherein the DNA sequence is introduced by naked DNA transfer.

21. The method of claim 1, 2 or 3, wherein the DNA sequence is introduced using an EYFP vector.

22. The method of claim 1, 2 or 3, wherein the DNA sequence is introduced by means of direct injection into a smooth muscle wall.

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23. The method of claim 22, wherein the smooth muscle is the bladder.

24. The method of claim 1, 2 or 3, which further comprises transfecting cells *ex vivo* and transplanting the transfected cells into the subject.

25. The method of claim 1, 2 or 3, wherein the subject has heightened contractility of a smooth muscle and regulation of the tone of the smooth muscle results in less heightened contractility of the smooth muscle in the subject.

26. The method of claim 25, wherein the smooth muscle cells are penile smooth muscle cells or bladder smooth muscle cells.

27. The method of claim 1, 2, or 3, wherein the subject has a dysfunction selected from the group comprising asthma; benign hyperplasia of the prostate gland (BPH); coronary artery disease; erectile dysfunction; genitourinary dysfunction of the endopelvic fascia, prostate gland, ureter, urethra, urinary tract, or vas deferens; gastrointestinal motility disorder; constipation; diarrhea; irritable bowel syndrome; migraine headache; premature labor; Raynaud's syndrome; urinary incontinence; bladder dysfunction; varicose veins; and thromboangitis obliterans.

28. The method of claim 27, wherein the dysfunction is an erectile dysfunction.

29. The method of claim 11, wherein the subject has an erectile dysfunction.

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30. The method of claim 28 or 29, wherein the erectile dysfunction results from incomplete relaxation of smooth muscle due to neurogenic dysfunction, arteriogenic dysfunction, and/or veno-occlusive dysfunction.

31. The method of claim 27, wherein the dysfunction is a bladder dysfunction.

32. The method of claim 31, wherein the bladder dysfunction results from bladder overactivity.

33. The method of any one of claims 27-32 wherein the dysfunction is treated.

34. The method of claim 1, 2 or 3, wherein the potassium channel protein is not normally expressed in the smooth muscle cells.

35. A method of treating erectile dysfunction in a subject, comprising the introduction and expression of a DNA sequence comprising a smooth muscle specific promoter, smooth muscle alpha actin (SMAA), operably linked to a sequence encoding a potassium channel protein that regulates corporal smooth muscle tone, in a sufficient number of corporal smooth muscle cells of the subject to regulate corporal smooth muscle tone in the subject and thereby treat the subject's erectile dysfunction.

36. The method of claim 35, wherein the potassium channel protein is maxi-K,  $K_{ATP}$ , Kv1.5, or SK3.

37. A method of treating erectile dysfunction in a subject, comprising the introduction and expression of a DNA sequence encoding a voltage-dependent potassium channel protein that regulates corporal smooth muscle

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tone, in a sufficient number of corporal smooth muscle cells of the subject to regulate corporal smooth muscle tone in the subject and thereby treat the subject's erectile dysfunction.

38. The method of claim 37, wherein the voltage-dependent potassium channel protein is Kv1.5.

39. A method of treating erectile dysfunction in a subject, comprising the introduction and expression of a DNA sequence encoding a non-large-conductance, calcium-sensitive potassium channel protein that regulates corporal smooth muscle tone, in a sufficient number of corporal smooth muscle cells of the subject to regulate corporal smooth muscle tone in the subject and thereby treat the subject's erectile dysfunction.

40. The method of claim 39, wherein the non-large conductance, calcium-sensitive potassium channel is an intermediate conductance calcium-sensitive potassium channel.

41. The method of claim 39, wherein the non-large conductance, calcium-sensitive potassium channel is a small conductance calcium-sensitive potassium channel.

42. The method of claim 41, wherein the small conductance calcium-sensitive potassium channel is SK3.

43. The method of claim 1, wherein using the smooth muscle specific promoter SMAA operably linked to a DNA sequence encoding the potassium channel protein is at least as effective in regulating smooth muscle tone in a subject as using a viral promoter operably linked to the DNA sequence encoding the potassium channel protein.

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44. The method of claim 35, wherein using the smooth muscle specific promoter SMAA operably linked to a DNA sequence encoding the potassium channel protein that regulates corporal smooth muscle tone is at least as effective in treating erectile dysfunction in a subject as using a viral promoter operably linked to the DNA sequence encoding the potassium channel protein.